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TRANSMITTAL FORM

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Filing Date	08/16/2001
First Named Inventor	Larry Paskar
Group Art Unit	3762
Examiner Name	M. Bockelman
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ENCLOSURES *(check all that apply)*

- ☐ Charge Deposit Account –08-3460
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declarations(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
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- ☐ Petition For Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR 1.137(b))
- ☐ Assignment Papers *(for an Application)*
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- ☐ After Allowance Communication to Group
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Signature	Karen K. Sonsteby	Date	01/30/07

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: L. Paskar

SERIAL NO.: 09/931,466

FILED: 8/16/2001

FOR: Catheter with Out-of-plane Configurations

GROUP ART UNIT: 3762

EXAMINER: M. Bockelman

DOCKET NO.: 74442.01

Confirmation No. 3794

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Attention: Board of Patent Appeals and Interferences

FIRST AMENDED APPELLANT'S BRIEF

In response to the Notice of Non-Compliant Appeal Brief dated January 3, 2007, Applicant submits the following amended appeal brief. Applicant has addressed the issues raised in the Notice and has not added any new subject matter in this amended appeal brief.

The fees required under § 1.17, and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying transmittal form.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the party named in the caption of this brief, namely Larry D. Paskar, M.D.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal:

there are no such appeals or interferences.

III. STATUS OF CLAIMS

The status of the claims in this application is the total number of claims in application

The total claims in the application are 1-34.

Status of the Claims

1. Claims cancelled: 1-18, 23, 25, 27, 30, 31, 33 & 34.
2. Claims withdrawn from consideration but not cancelled: none.
3. Claims pending: 19-22, 24, 26, 28, 29, & 32.
4. Claims allowed: None.
5. Claims rejected: 19-22, 24, 26, 28, 29, & 32.

Claims on Appeal

The claims on appeal are 19-22, 24, 26, 28, 29, & 32.

IV. STATUS OF AMENDMENTS

An amendment canceling claims 10-16, 31, 33 and 34 is filed herewith and is proper under MPEP § 106 in that the amendment only cancels claims and does not affect the scope of any other pending claim in the proceeding.

No other amendments are pending.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claims on appeal are all in general directed to methods using combination catheters to form "out-of-plane" shapes.

As will become apparent below, the prior art cited by the Examiner is primarily directed to pointing rather than shaping. And none of the art teaches the unexpected result—the formation of out-of-plane shapes when curved distal end portions of inner and outer elements interact—that form the basis of these claims. From two relatively simple elements—an inner element and an outer tube, Dr. Paskar (the present inventor) has developed a catheter that may be shaped into numerous shapes that in the prior art are achievable only by using a plurality of separate, pre-shaped catheters.

Claim 19 is illustrative of these claims. It requires disposing a catheter tube in a human body, which catheter tube has a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane, disposing an inner medical element in the catheter tube, said inner medical element having a distal end, and forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. Note, specifically that the step of disposing the inner medical element in the catheter tube and the step of forming the combination catheter into an out-of-plane shape are two separate steps. Moreover, the language of the claim specifically requires that the distal end portion of the catheter tube be planar (having an axis lying in a single plane). Therefore, any non-planar portion of the catheter tube is, by definition, not the claimed "distal end portion."

This claimed out-of-plane feature is illustrated below. Fig. 15 from the present application is an elevation in which the inner medical element 35 is coming out of the plane of the paper. Fig. 15A is a top plan view in which "P" is the plane of the paper in Fig. 15 and inner medical element 35 is clearly illustrated as coming out of the plane P. Fig. 15B is a perspective line drawing showing various out-of-plane shapes achievable by the present invention. It should be appreciated that out-of-plane shapes are useful not because they point in particular directions (a simpler shape pointing in the same direction can always be found), but because those shapes provide an "anchoring" or "wedging" effect that maintains the combination catheter in a desired position in the body. As will appear, the prior art cited against these "out-of-plane" claims are directed to aiming, not shaping.

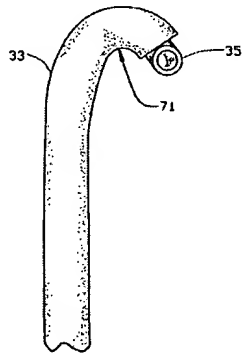


FIG. 15

Front Elevation

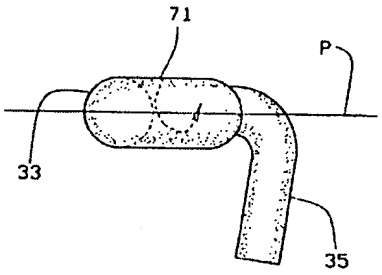


FIG. 15A

Top Plan

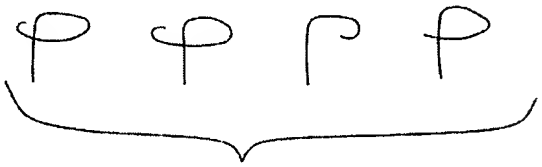


FIG. 15B

Line Drawings of Out-of-Plane Shapes

In these figures, the portion of the catheter tube adjacent the distal end of the catheter tube defines a distal end portion of the catheter tube 33, said distal end portion assuming and maintaining a curved configuration such that the distal end portion of the catheter

tube is disposed substantially in a first plane. The first plane P is illustrated in Fig. 15A of the present application, above. Note that the distal end portion of catheter tube 33 is disposed in plane P, while the distal end portion of inner element 35 is disposed substantially out of plane P. Stated another way, the plane P defines the distal end portion of the catheter tube, which may include one or more curved and/or straight sections.

When the inner catheter or element is fixed at some intermediate rotational position, such as ninety degrees, with respect to the distal end portion of the outer tube, as illustrated above, the out-of-plane shapes of the present invention result. The curved nature of the inner element in this circumstance causes the exposed end of the inner element to be substantially out of the plane P containing the distal end portion of the outer tube. A whole family of these "out of plane" curves can be achieved as desired by the user by curving the outer tube more or less and exposing more or less of the inner catheter or element as illustrated above in Fig. 15B. Figs. 15-15B illustrate an important and unexpected feature of the present invention—rotational change in the relationship of an inner element with a distal curved portion and an outer tube with a distal curved portion change the shape of possible combination catheter configurations obtainable so that out-of-plane shapes are achieved.

At an interview in one of the parent cases, models were demonstrated to the Examiner of the present application illustrating the various families of curves achievable with the present invention. An offer to leave the models with the Examiner was declined by the Examiner. Subsequently, models were sent to the Examiner and applicant has repeatedly offered to demonstrate those models to the Examiner. Those offers, and

multiple requests for interviews, have been refused. The models will greatly facilitate the Board's understanding of the issues on this appeal, as will the enclosed DVD demonstrating a computerized simulation of the use of the models. (The DVD contain exactly the same material as a videotape previously provided to the Examiner.) A hearing before the Board to explain these issues and the patentable subject matter is respectfully requested.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 19-22 are unpatentable under 35 U.S.C. 102(b) over U.S. Patent 4,430,083 to Ganz et al.

Whether claims 24, 26, and 28 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent 4,430,083 to Ganz et al. in view of U.S. Patent 3,970,089 to Saice.

Whether claims 19-22 are unpatentable under 35 U.S.C. § 102(b) as anticipated by (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of either Voda (U.S Pat. No. 5,445,625) or Weldon U.S Pat. No. 5,195,990) and Kiemeneij (U.S Pat. No. 6,723,083).

Whether claims 22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. § 102(b) as anticipated by (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of either Weldon U.S Pat. No. 5,195,990, Quinn (U.S. Patent 4,580,573), Carpenter (U.S. Patent 4,586,491), Saice (U.S. Patent 3,970,089) and Kiemeneij (U.S Pat. No. 6,723,083).

Whether claims 19-22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. 103(a) over Petruzzi (U.S. Pat. 4,474,174) in view of D'Amelio et al. (U.S. Pat. No. 4,659,195), Ueda (U.S. Pat. No. 4,617,914), and Takahashi reference manual.

Whether claims 19-22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. 103(a) over D'Amelio (U.S. Patent 4,659,195) in view of Ueda (U.S. Patent 4,617,914) further in view of Forester et al (U.S. Patent 4,905,667) or Patel (U.S. Patent 4,577,621).

Whether claims 22 and 29 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

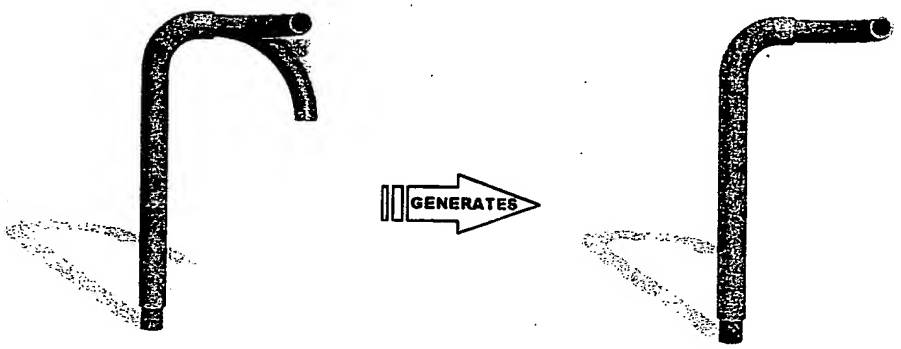
VII. ARGUMENT

The Examiner has cited twelve separate references in making six separate rejections of the claims. The MPEP, § 706.02 is very clear on this point, stating, "Merely cumulative rejections, i.e., those which would clearly fall if the primary rejection were not sustained, should be avoided." The same section of the MPEP also states, "Prior art rejections should ordinarily be confined strictly to the best available art." The only conclusion that can be reached from the Examiner's failure to heed these admonishments is that none of the rejections have merit.

In addition to the multiple rejections mentioned above, two of the rejections are presented in an alternative format (i.e., anticipated or obvious). Each rejection has also been presented as a "blanket rejection" (i.e., lacking explanation as to the relevance of the reference to each claim and an analysis of the elements of the claim in view of that reference). As a result, the grounds of rejection for each claim cannot be ascertained.

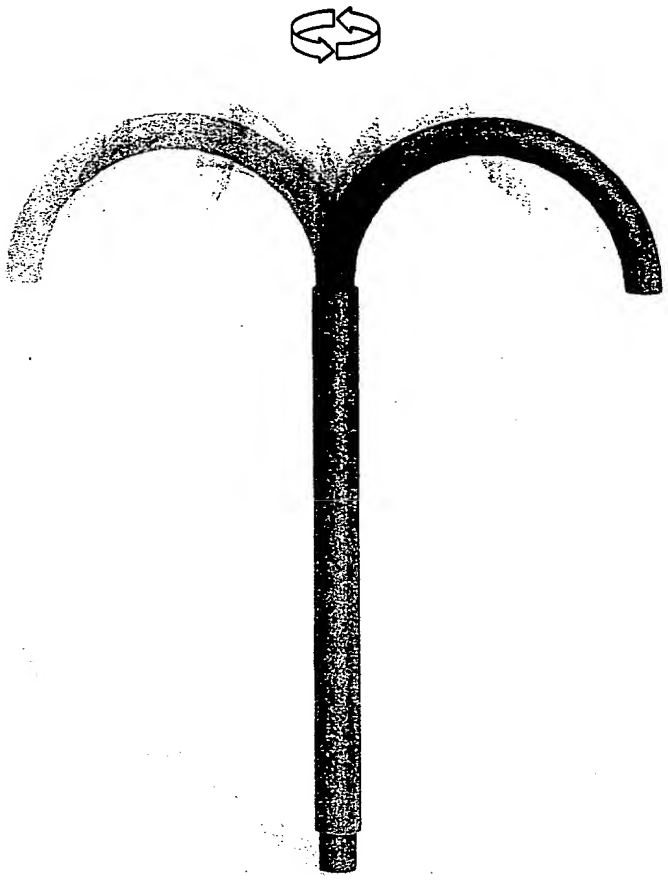
Accordingly, the Examiner has failed to provide a prima facie case against patentability of any of the claims. Applicant traverses these rejections, as discussed below, but asserts that the presentation of multiple rejections under alternative theories is merely indicative of the similar devices in the art, not evidence of the present invention.

The fundamental difference between the prior art and the present invention may be more readily understood by considering the following drawings, which illustrate the presently claimed formation of an out-of-plane shape by the interaction of two curved distal end portions.



By rotating the inner element 90 degrees with respect to the outer catheter from the downward facing position shown to the left in the drawings above, one generates the out-of-plane shape shown to the right. This should be contrasted with the prior art in which the distal end of the outer tube is straight. Rotation of the prior art inner catheter with respect to the outer (straight) outer tube does not, and cannot, result in an out-of-plane shape, as illustrated by the drawing below:

Prior Art



As will appear below, the Examiner repeatedly ignored fundamental limitations of the claims. This is illustrated in the Examiner's rejection of the claims under § 103 over the Sylvanowicz reference (discussed below).

The Examiner's approach of ignoring claim limitations is fundamentally flawed and is repeated throughout the Office action. Specific examples are discussed in the discussions of the rejections below.

Fundamental to many of the Examiner's rejections is the fact that he fails to recognize that the claims define the "distal end portion" as planar, which excludes from

consideration many if not all of the references and combinations cited by the Examiner, as is explained in detail below.

The Examiner also errs in his conclusions that something is "inherent" in the cited art. A most egregious example of this is found in the Examiner's conclusion that the "out-of-plane" feature of certain of the claims is inherently present in the cited art, specifically Sylvanowicz (discussed in the appropriate section below). As a preliminary matter, it should be noted that (as explained below) this construction of Sylvanowicz is inconsistent with the claim requirement that the distal end portion of the catheter tube be planar. Moreover, the Examiner's conclusion cannot be true, as shown by the Examiner's actions in one of the parent applications of the present application. In application Serial No. 07/834,007, the Examiner refused to accept new drawings showing the out-of-plane feature stating:

> "The curves that are generated as shown in new figures 13-15B would not necessarily be expected based upon the original disclosure." (p. 2 of Office action dated 11/19/92).

If this was true of applicant's disclosure at the time, it is certainly true of Sylvanowicz. The out-of-plane feature is not inherent and, therefore, Sylvanowicz does not teach the out-of-plane feature of these claims.

This example of misconstruing a reference solely for the purpose of rejecting patent claims is improper and should not be condoned. Other examples of misconstruing the references are found throughout the detailed discussions of the rejections below.

Although the types of errors committed by the Examiner are numerous, another significant one is that in the obviousness rejections the Examiner has completely failed to

show any motivation in the art for making the modifications and combinations he suggests. This error is repeated throughout the obviousness rejections. It is only through improper use of hindsight, by using the present invention, that the Examiner is able to make the suggested combinations.

In summary, the Examiner in the Office action below routinely ignored claim limitations, mischaracterized the art, and postulated motivation to modify and combine the art where none existed. All the rejections should be reversed.

REJECTIONS UNDER 35 U.S.C. § 102

Whether claims 19-22 are unpatentable under 35 U.S.C. 102(b) over U.S. Patent 4,430,083 to Ganz et al.

Ganz et al. discloses a system which uses **two separate inner catheters to catheterize the two passageways.** These catheters are labeled 11a and 11b in Ganz. See col. 7, lines 24-33 for a description of inner catheter 11a, and col. 7, lines 45-57 for a description of inner catheter 11b. Element 105 in Ganz is in fact merely a preformed bend in inner catheter 11a. The two different inner catheters have different configurations, as revealed by the following passage. See col. 6, lines 40-57, which state:

> "The only difference between the catheters 11 and 11a is in the configuration of the distal end portions. Specifically, the distal end portion 47 is straight, whereas the **distal end portion 47a has** two resilient orientation bend sections 101 and 103 and **a passage-seeking bend section 105** which is also resilient. The passage-seeking bend section 105 is **configured to seek out the left anterior descending coronary artery** 107 (Fig. 12). The orientation bend **sections 101 and 103 automatically orient the passage-seeking bend section 105** when the

catheter 11a is used within an angiography catheter, such as an angiography catheter 57a (Fig. 12) which is designed for exploring the left coronary arteries." (Emphasis added)

In Ganz, the orientation bends 101 and 103 cooperate with the bends in the outer catheter 57a to **automatically** orient the bend section 105 in the proper direction to seek out the left anterior descending coronary artery—the inner catheter is not designed to be rotatable, it is designed to emerge at a single, unchanged orientation. Rotation of an inner catheter in Ganz with respect to the outer catheter would either break one of the components of the catheter or violate its intended purpose—neither of which would be desirable. Figures 12 and 13 of Ganz are shown below for ease of understanding:

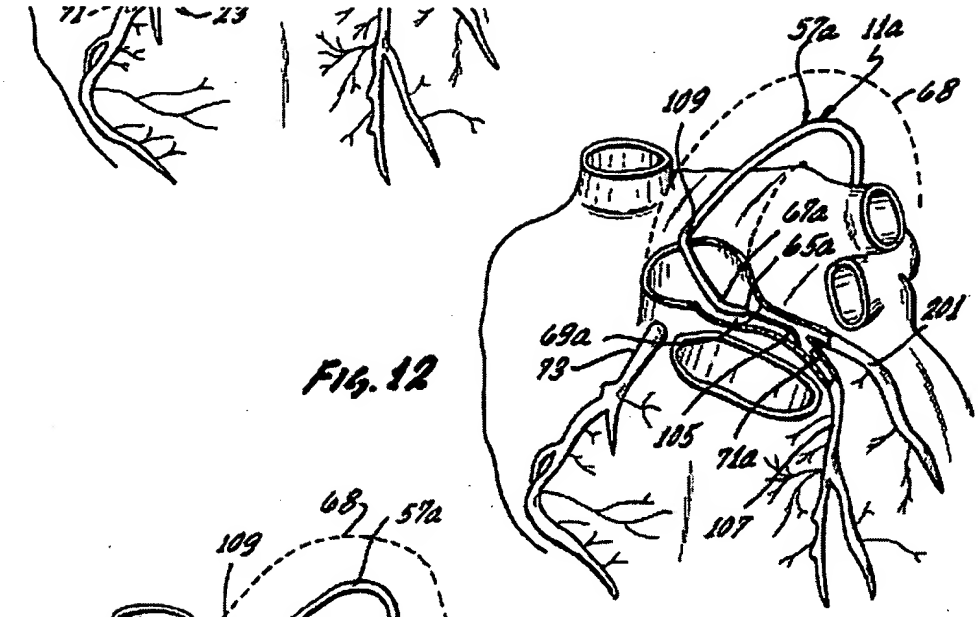


Fig. 12

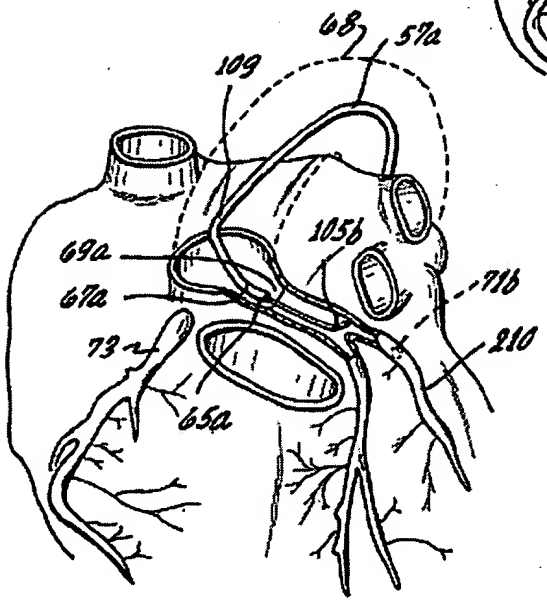


Fig. 13

Rather than teach rotating inner catheter 11a with respect to the outer catheter to obtain the configuration of Fig. 13, Ganz teaches using a completely new inner catheter 11b to create that shape. Col. 7, lines 45 to 53 states:

"Fig. 8 shows a **catheter 11b** which **is identical to the catheter 11a, except** that the **bend section 105b is displaced 180 degrees from the bend section 105.** The catheter 11b can be used with the angiography catheter 57a as shown in Fig. 13 in the same manner as described above with reference to Fig. 12. In terms of

operation, the only difference is that the **bend section 105b emerges from the distal opening 65a approximately 180 degrees displaced from the bend section 105**." (Emphasis added).

Claim 19 is an independent claim that requires the step of "disposing an inner medical element in the catheter tube" and the additional step of "forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element." Ganz et al. does not provides such a feature. In Ganz, the inner catheters are shaped so that the step of disposing the inner catheter in the outer tube forms the desired shapes. There is no separate "forming" step in Ganz. Claim 19 is allowable for this reason. Claims 20-22, 24 and 26 depend from and relate back to claim 19 and are allowable therewith. Claim 21 further requires reforming the distal end of the combination catheter into a substantially different shape. As discussed above, Ganz et al. requires a different inner catheter 11b to form the substantially different shape. The present invention is, therefore, a substantial improvement over Ganz et al. Claim 22 depends from claim 21 and further specifies that the reformed combination catheter is used in a medical procedure while the distal end of the combination catheter is in the reformed shape. Ganz et al. requires two separate inner catheters (11a and 11b) to obtain two different shapes. The present invention reforms the catheters already in place. The vast savings in time and expense, and the resulting improvement in patient outcomes should be apparent.

Whether claims 19-22 are unpatentable under 35 U.S.C. § 102(b) as anticipated by (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S.

Pat. No. 5,267,982), alone or in view of either Voda (U.S Pat. No. 5,445,625) or Weldon U.S Pat. No. 5,195,990) and Kiemeneij (U.S Pat. No. 6,723,083).

With respect to these claims, the Examiner has taken the position that Sylvanowicz inherently shows the "out of plane" feature (although it is never discussed) and the "fixing" requirement of the claims. It should be noted that

> "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.' *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1368, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). 'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *Id.* at 1269, 20 USPQ2d at 1749."

In re Robertson, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). As will be shown, the Examiner has not even shown a possibility that Sylvanowicz has these features. The Examiner's construction ignores the requirement of these claims that the "distal end portion" be planar, as defined. Certainly there is no showing (1) that the out of plane feature is "necessarily present" in Sylvanowicz, or that (2) "it would be so recognized by persons of ordinary skill in the art." Nor has he shown that the fixing feature is necessarily present or that its presence would be recognized for those of ordinary skill in the art.

The Examiner asserts that in moving the Sylvanowicz catheter from the figure 12 position to the figure 14 position it must inherently pass through an out of plane configuration.

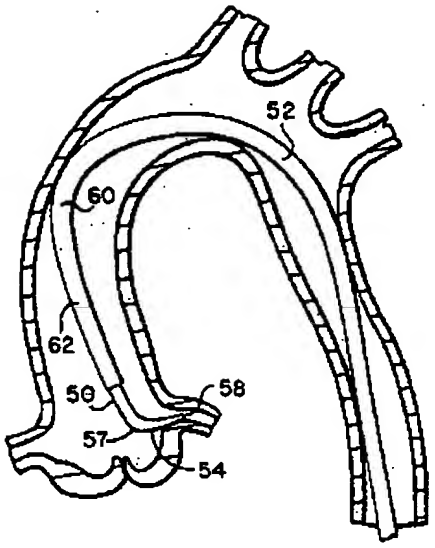


Fig. 12

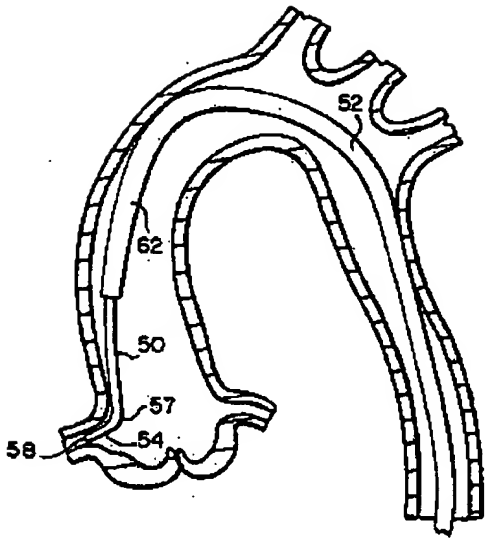


Fig. 14

But this approach also ignores a fundamental limitation of the claim. Claim 19 (and the other claims at issue) clearly requires that the "distal end portion" of the catheter tube assume and maintain a curved, planar configuration. Note the reference is not to the "distal portion", but to the "distal end portion". The Examiner's interpretation of the Sylvanowicz reference might have some merit if the limitation were the "distal portion", since everything distal of the proximal end is a distal portion, but it is clearly erroneous since the limitation is the "distal **end** portion". "End" has a well-recognized meaning, which the Examiner has routinely ignored. The Examiner refers not to the distal end portion of Sylvanowicz, but rather to some intermediate portion that suits his purposes.

As the above drawings from Sylvanowicz clearly show, the distal end portion 62 of catheter tube 52 in Sylvanowicz is straight in Fig. 12 and in Fig. 14, and there is no

indication that the distal end portion 62 is curved at any time in moving from the Fig. 12 position to the Fig. 14 position. In fact, Sylvanowicz specifically identifies portion 62 as "a **straight distal segment** 62 extending from the curved portion 60." (col. 6, ll. 53-56)(Emphasis added). Note that this is consistent with the requirement of claim 19 that the distal end portion be planar since a straight line always lies in a plane.

Thus, the distal segment of Sylvanowicz **that includes the end**, i.e., the distal end portion, is straight, not curved. Since the distal end portion of the catheter tube in Sylvanowicz is straight, it is incapable of providing the surprising interaction of two curved distal end portions which results in the inner element being thrown out of plane with respect to the outer catheter tube.

The Examiner takes the position that in moving from the Fig. 12 to the Fig. 14 position, the catheter must go out-of-plane. But that conclusion is false. The present claims clearly define the plane with respect to the **curved distal end portion** of the outer catheter, not with respect to the outer catheter as a whole. It is only by ignoring the plain language of the claim and of Sylvanowicz ("**straight** distal segment 62") that the Examiner is able to reach his erroneous conclusion as to what must happen.

Similarly, the Examiner recognizes that the configuration of Fig. 12 in Sylvanowicz is planar, but appears to take the position that the other configuration (that of Fig. 14) must be out-of-plane. The Examiner is incorrect, as can be easily demonstrated. In col. 7, lines 25-30, and 46-52 of Sylvanowicz, formation of the configuration for entering the right coronary artery ostium (the configuration of Fig. 14 is described, as follows:

"Such withdrawal shifts the location of the primary curve proximally along the length of the catheter which cause a repositioning of the **distal portion of the inner catheter** so that it **points toward the right coronary ostium**."

"By withdrawing the outer tube proximally to reposition the primary curve, **the distal segment 62 [of the outer tube]** is reoriented and **points toward the right coronary ostium**. Thus, when extended, the position of the protruding distal portion of the inner catheter shifts from the position as shown in FIG. 12 toward a position toward the right coronary ostium." (Emphasis added)

Note that the inner catheter in Sylvanowicz is disposed in the outer tube and exits from the distal tip of distal end segment 62 (see Fig. 14, for example). These elements are, therefore, co-linear at the point where the inner catheter exits the outer tube. If the distal portion of the inner catheter points toward the right coronary ostium, and the straight distal segment 62 points toward the rights coronary ostium, then those two elements **must be in the same plane**. If they were not co-planar when in the Fig. 14 configuration, it would be physically impossible for both the distal segment 62 of the outer tube and the distal portion of the inner catheter to both point toward the right coronary ostium. Note that even if one includes a curved portion of the Sylvanowicz catheter in the "distal end portion" thereof, that curved portion is part of the distal end portion only if it is planar as defined in claim 19, and the plane said portion is located in is the plane of the right coronary ostium.

This difference between Sylvanowicz and the presently claimed invention is seen more clearly by examining the following figures from the present application.

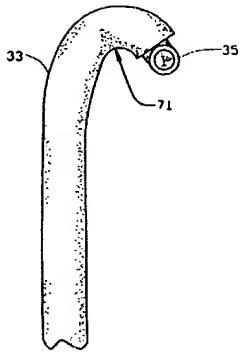


FIG. 15

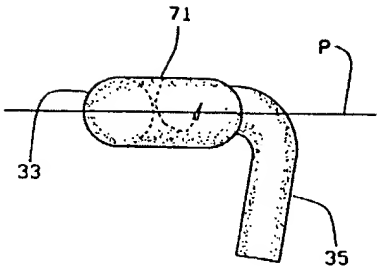


FIG. 15A

FIG. 15B

In Fig. 15 of the present application, the distal end portion of the catheter tube is clearly curved in the plane of the paper and the inner curved element, as a result, has its distal end portion thrown out of the plane of the paper (as shown in Fig. 15A). The two curves (that of the curved distal end portion of the catheter tube and that of the curved distal end portion of the inner element) are in two different planes, provide an overall out-of-plane shape as illustrated in Fig. 15B.

Contrast this with Sylvanowicz in which a single plane always contains the straight distal end portion 62 of the catheter tube and curved distal end portion 54 of the inner element, **even as the inner element is rotated from one position to the next**. The result is different in Sylvanowicz because the distal end portion 62 of the catheter tube is straight, not curved as required by the present claim. An infinite number of planes pass through the straight distal end portion 62 of the catheter tube in Sylvanowicz, and so in the Fig. 12 and Fig. 14 positions in Sylvanowicz and in all positions in between, the distal end portion 54 of the inner element lies in one of those planes.

The Examiner's position ignores the clear requirement of the present claims that the distal end portion of the catheter tube define a first plane (i.e., be planar in the sense

that is used in the present invention). Under the Examiner's construction of Sylvanowicz, the curved portion of Sylvanowicz is included in the "distal end portion". But, during rotation of the inner element with respect to the outer catheter tube in Sylvanowicz, not all of the curved portion of the outer tube remains in the same plane. It is, therefore, not a portion of the "distal end portion" as defined by these claims. Under the express language of claim 19, the portion of Sylvanowicz referred to by the Examiner includes portions which are not planar, and which therefore do not constitute the required plane-defining distal end portion.

Moreover, no one has recognized the huge advantages of being able to obtain this entire family of "out of plane" shapes from two curvable elements. In fact, such a construction is immensely useful. It permits two planar elements (the inner element and the outer tube) to interact to provide an out-of-plane position for the distal end. It should be recognized that out-of-plane positioning is extremely useful in the human body. Yet Sylvanowicz fails to even hint at this feature. The claimed feature is simply not inherent in Sylvanowicz.

The Examiner's inherency argument is further undercut by the history of the present invention. In Serial No. 07/834,007, one of the parent applications of the present application, the Examiner refused to accept new drawings showing the out-of-plane feature stating:

> "The curves that are generated as shown in new figures 13-15B would not necessarily be expected based upon the original disclosure." (p. 2 of Office action dated 11/19/92).

If this was true of applicant's disclosure at the time, it is certainly true of Sylvanowicz. Sylvanowicz simply does not teach the out-of-plane feature of these claims.

The Examiner is simply wrong. He has ignored claim limitations fundamental to the claimed invention, and he has "found" inherency where none in fact exists. These claims are allowable over Sylvanowicz for all these reasons. Because of both the language of the claims and the relevant Federal Circuit precedent, this claim is allowable over Sylvanowicz.

The Examiner has also taken the position that Sylvanowicz shows the "fixing" requirement of these claims in the presence of an anti-leak device, even though that device permits relative rotation and translation of the two tubes in Sylvanowicz. How a device that permits (and in fact is designed to permit) relative rotation and translation between these two elements can be said to "fix" those two elements is truly a mystery. For example, Sylvanowicz contains, among others, the following passages concerning translation and rotation of the inner catheter with respect to the outer tube while both are disposed in the human body:

Col. 7, lines 20-23	"Thus, the inner catheter may be rotated along its longitudinal axis so that it is directed selectively toward the left coronary ostium or the right coronary ostium."
Col. 7, lines 23-30	"Additionally, the configuration of the distal portion of the catheter assembly may be controlled by withdrawing the catheter

	outer tube proximally over the inner catheter. **Such withdrawal shifts the location of the primary curve proximally along the length of the catheter which causes a repositioning of the distal portion of the inner catheter so that it points toward the right coronary ostium.**" (Emphasis added)
Col. 7, lines 43-48	"Thus, as illustrated in Fig. 13, the outer tube 52 has been withdrawn so that the position of the primary curve relative to the distal end of the catheter is moved proximally. By withdrawing the outer tube proximally to reposition the primary curve, **the distal segment 62 is reoriented and points toward the right coronary ostium.**" (Emphasis added)
Col. 7, lines 52-57	"The inner catheter 50 may be rotated about its longitudinal axis approximately 180° to direct the distal tip 58 toward the right coronary ostium so that as the distal portion of the catheter 50 continues to shift it will bring the tip 58 into the right

	coronary ostium."

Note that all of this relative manipulation (rotation and translation of the outer tube and inner catheter take place in the human body, **yet the patient does not bleed to death.** Apparently (and obviously) the hemostasis valve relied upon by the Examiner is on the entire time. The hemostasis valve, therefore, does not provide the required fixing.

Claim 19 is an independent claim that requires "forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element." As explained above, Sylvanowicz does not have the out-of-plane feature as claimed, and has no suggestion of using a catheter having such an out-of-plane configuration in a medical way.

Claims 20, 21, and 22 depend from claim 19 and are allowable therewith.

For all these reasons, these claims are all allowable over Sylvanowicz.

Whether claims 22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. § 102(b) as anticipated by (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of either Weldon U.S Pat. No. 5,195,990, Quinn (U.S. Patent 4,580,573), Carpenter (U.S. Patent 4,586,491), Saice (U.S. Patent 3,970,089) and Kiemeneij (U.S Pat. No. 6,723,083).

Claim 22 was discussed in the section immediately above.

Claims 24, 26, and 32 depend from claim 19 and are allowable therewith. Claims 24 and 26 require proximal fixing, which, as explained above, is totally absent from Sylvanowicz.

Claim 28 is another independent claim. This claim includes the fixing feature and is allowable for the same reasons as claims 24 and 26.

Claim 29 is also independent and includes the out-of-plane and fixing requirements of claim 28. It also provides for forming the combination catheter into a second shape, in which the distal end of the combination catheter is also in an out-of-plane shape, and fixing the inner medical element against translation and rotation while the combination catheter is in that shape. Sylvanowicz lacks fixation in a single out-of-plane shape, so it certainly does not teach fixation in two different out-of-plane shapes. Claim 29 is allowable for all these reasons.

Claim 32 depends from claim 19 and is allowable with that claim. Claim 32 is also allowable because it specifies that the forming step includes rotating the inner medical element with respect to the catheter tube.

For all these reasons, these claims are all allowable over Sylvanowicz.

REJECTIONS UNDER 35 U.S.C 103(a)

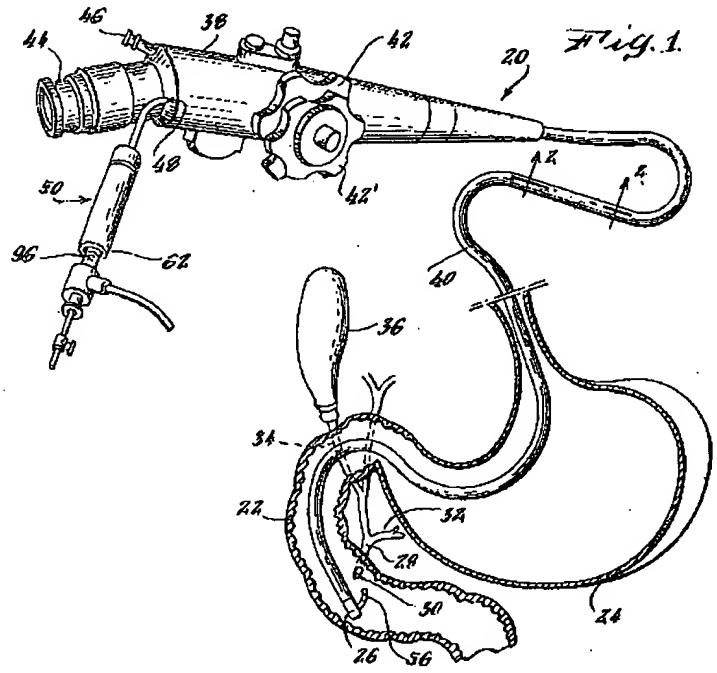
Whether claims 24, 26, and 28 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent 4,430,083 to Ganz et al. in view of U.S. Patent 3,970,089 to Saice.

Claim 24 depends from claim 19 and provides for proximally fixing the distal end of the combination catheter substantially out of the first plane. Ganz et al. does not have this feature. Moreover, there is no reason to add such a feature to Ganz et al.—also as discussed above. Claim 26 similarly requires proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. This feature is not shown or suggested in this art. Saice adds nothing to Ganz, since there would be no motivation to add such a feature. Ganz discloses a system where the inner catheter(s) and the outer tube are formed to have a particular orientation with respect to each other. The particular configurations of the Ganz elements result in "fixing" at the distal end of the catheter, not at the proximal end. Proximal fixing, as required by these claims, is irrelevant to the system of Ganz.

Claim 28 is an independent claim that includes the step of "forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element", and the step of "proximally fixing the inner medical element against translation and rotation with respect to the catheter tube." As discussed above, Ganz et al. lacks any proximal fixing feature, and does not need such a feature. There is no motivation in the art to combine the references as suggested by the Examiner, and in fact the structure in Ganz et al. teaches away from such a combination. Claim 28 is allowable for all these reasons.

Whether claims 19-22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. 103(a) over Petruzzi (U.S. Pat. 4,474,174) in view of D'Amelio et al. (U.S. Pat. No. 4,659,195), Ueda (U.S. Pat. No. 4,617,914), and Takahashi reference manual.

Petruzzi can best be understood from an examination of its drawings. Fig. 1 is set forth below:



As can clearly be seen in this drawing, Petruzzi has a straight distal portion of the outer tube whose longitudinal axis is in the same plane as the distal portion of a curved inner element 56. (As discussed in connection with Sylvanowicz, if one goes back further on Petruzzi from the distal end, the catheter is no longer in the same plane and hence that portion does not constitute the claimed "distal end portion" which defines a plane.) As shown in Fig. 3, below, the inner element can be extended out through an opening in the side of endoscope 40 and its curve may be changed by means of a movable wedge 92.

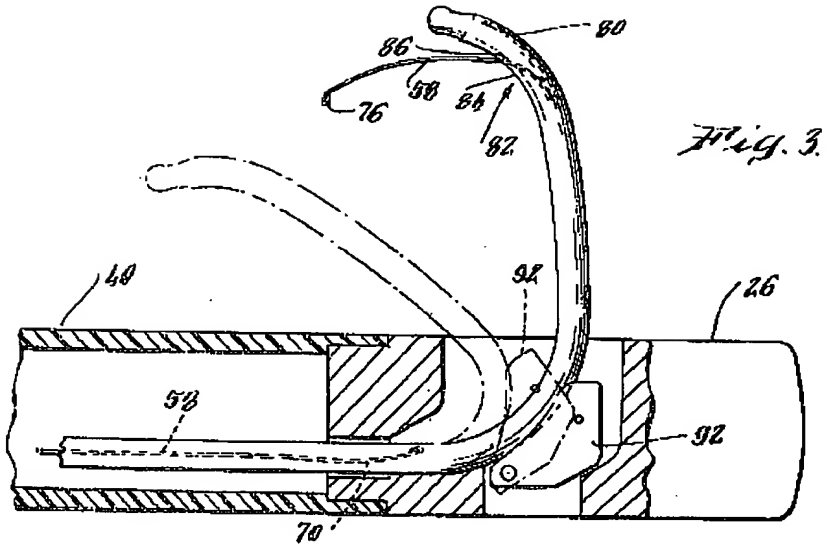


Fig. 3.

Curved element 56 and a tool 58 contained therein are shown in more detail in Fig. 3 from Petruzzi, set forth above (curved element 56 being unlabeled in Fig. 3, but being identified in Fig. 1). Note that there is no indication the inner element 56 in Petruzzi will occupy any plane other than the one defined by the longitudinal axis of the outer tube. In fact, in Fig. 1 of Petruzzi the window or opening in the endoscope (shown but not labeled in Fig. 3 above) through which member 56 extends cannot be seen, thereby indicating that the plane defined by the distal end portion of outer element is not in the plane of the paper, but rather is in some other plane—presumably the one including element 56 and a valve 30 known as the ampulla of Vater.

The Examiner takes the position that Petruzzi must show the claimed out-of-plane configuration of the present invention, stating:

"As a result of the relative positions, it is seen as a requirement that the outer tubular member of Petruzzi must be used to position the endoscope in a left right

manner relative [corrected] to the page while the catheter 56 is bent and or manipulated to guide its tip into the page so as to access the ampulla of Vater. Such a manipulation requires the inner medical 56 60 be positioned out of the plane to the bent curved portion of the outer endoscope. It is apparent to those of ordinary skill in the art that such an out of plane configuration would be necessary in order to access the [ ] ampulla of Vater."

The reference to "60" in this statement by the Examiner is not understood since it appears that "60" is an internal, conductive control wire that has no bearing upon the claimed out-of-plane feature. More importantly, the Examiner is wrong. The drawings of Petruzzi, namely Fig. 1, which hide the opening in the endoscope that faces the ampulla of Vater are inconsistent with the Examiner's speculation but are totally consistent with a manipulation which result in the distal end, the window, and the guiding catheter of Petruzzi being "in plane", not out-of-plane as required by these claims. The affidavit of Dr. Giuseppe Aliperti, filed with the Amendment dated November 4, 2005, reveals that the Examiner's construction of Petruzzi is incorrect and totally inconsistent with actual devices, whereas the applicant's construction of Petruzzi is totally consistent with real world devices. This evidence, which is unrebutted, conclusively establishes that the Examiner has misconstrued Petruzzi and that the rejection thereon should be reversed.

Moreover, the claimed out-of-plane shape of the distal end in Petruzzi, as explained below, is unachievable since the distal end is straight, solid, and unbendable. This is shown in Fig. 3 of Petruzzi. That Figure is set forth below.

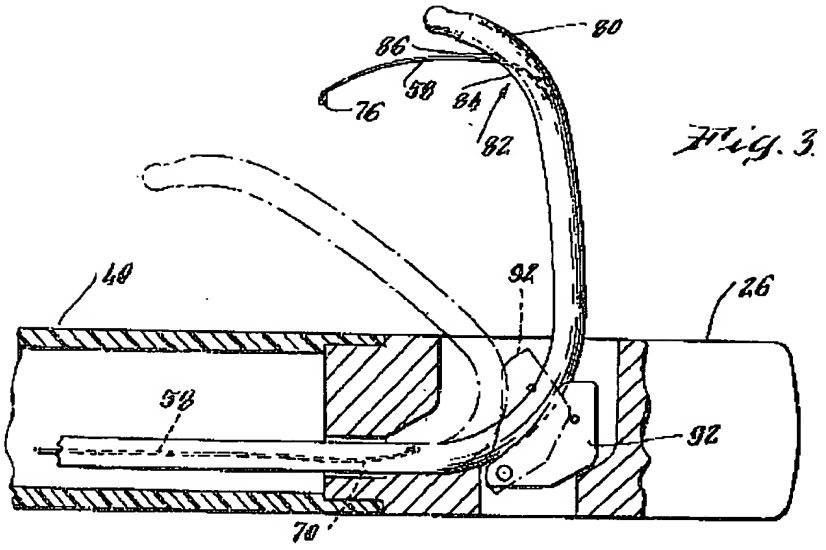


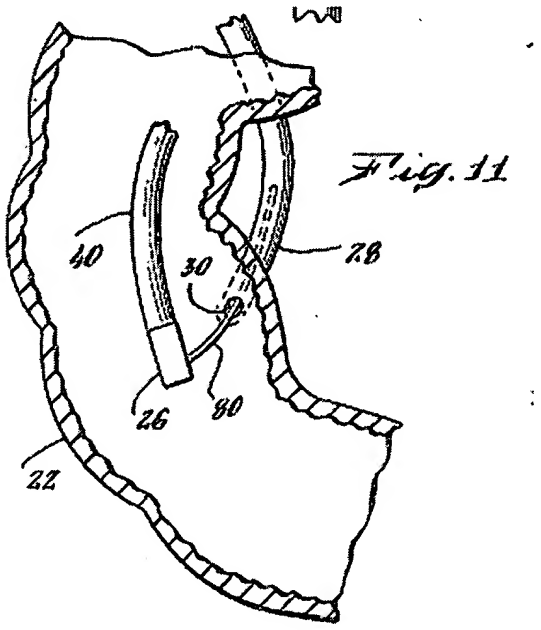
Fig. 3.

Note that there is absolutely no mechanism in Petruzzi to cause the distal end portion to bend in any way. It is solid. The inner catheter that comes out of the side of this straight, solid portion is bendable by the wedge 92, but there is no similar mechanism for forming a curve in the distal end portion of the outer tube. Note as well that the movement of element 82 in Petruzzi is in the plane of the window of the outer catheter. It appears that the structure of Petruzzi, as would be expected, in fact mechanically confines element 82 to stay in plane. Moreover, there is absolutely no structure provided to move element 82 out of that plane.

With the apparatus of Petruzzi, the only way to direct the catheter to the ampulla of Vater is by pointing the window of the endoscope straight toward the ampulla. This is a matter of basic physics. If the window of the endoscope were positioned in a left/right manner as theorized by the Examiner, the medial wall (and not the posterior wall containing the ampulla) would be visualized. In that case, since the ampulla would not be in sight, it could not be catheterized. If the window were not pointing at the ampulla,

the user would not have any idea where to direct the catheter. And if the catheter were disposed out-of-plane with respect to the window/ampulla plane, it would not (could not) go into the ampulla.

Importantly, one should note that one does not see the window in Fig. 1 or Fig. 11 of Petruzzi, which is totally consistent with the window and the optics facing the ampulla in the posterior wall—allowing the catheter to be extended *in the plane* of the window and ampulla so that all elements are clearly in a single plane. For convenience, Fig. 11 of Petruzzi is shown below:



With the Petruzzi device, unless the object (in this case the ampulla of Vater) is in line of sight view, it cannot be catheterized. The Examiner's theory of events—looking in one direction and catheterizing in another which you cannot see and do not know the location of—is impossible with the Petruzzi device. Petruzzi *could* show many things, but it does not show or suggest this invention.

Claim 19 is an independent method claim that requires the defined out-of-plane feature. As explained above, Petruzzi completely lacks this feature. Claims 20-22, 24, and 26 depend from or relate back to claim 19 and are allowable therewith. In addition, claim 20 includes the step of positioning the combination catheter in a desired position, and using the combination catheter in a medical procedure while the distal end of the combination catheter is disposed substantially out of the first plane. None of the cited references disclose the out-of-plane feature, so they by definition lack the feature of using the combination catheter in a medical procedure while the distal end of the combination catheter is out-of-plane.

The present invention allows the formation of various out-of-plane shapes in the body, as needed, for various medical procedures, and then the use of the formed shape in the medical procedure. The Petruzzi reference does not. Rather, it shows pointing in a desired direction and extending the inner catheter—not shaping. This feature is emphasized even more in claim 21 which further requires the step of reforming the distal end of the combination catheter into a substantially different shape, and in claim 22 in which the combination catheter is used in a medical procedure while the distal end of the combination catheter is in the reformed shape. Claim 24 provides for proximally fixing the distal end of the combination catheter substantially out of the first plane. As explained above in connection with Sylvanowicz, this proximal fixing feature is not found in the art. (Note, for example, that in Cho the outer element 15 is straight, so it does not define the first plane and hence there can be no fixation of the distal end of the combination catheter substantially out of the first plane. Conversely, if the duodenoscope 51 is considered the outer tube, there is no mechanism for fixing the catheter with respect

to the duodenoscope.) In addition, note that D'Amelio et al teaches proximal fixing against translational movement, but does not teach proximal fixing against rotation (which is required to fix "the distal end of the combination catheter substantially out of the first plane" as required by this claim. Claim 26 further provides for proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As discussed immediately above, D'Amelio et al teaches translational fixing, but not rotational fixing. Claims 20-22, 24 and 26 are allowable for these reasons as well.

Claim 28 is another independent method claim that includes the out-of-plane feature of claim 19, as well as the proximal translational and rotational fixing feature of claim 26. Claim 28 is, therefore, allowable for all the same reasons as those claims.

Claim 29 is an independent method claim directed to forming the combination catheter into first and second out-of-plane shapes and proximally fixing those shapes for periods of time sufficient to permit medical use. None of the references teaches proximal fixing for even a single out-of-plane shape, much less two. More significantly, the prior art is mute concerning forming first and second out-of-plane shapes. Claim 29 is unquestionably allowable.

Claim 32 depends from claim 19 and also is directed to the feature of forming the shape by rotating the inner medical element with respect to the catheter tube. The art lacks this feature, so claim 32 is allowable for this reason as well.

Whether claims 19-22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. 103(a) over D'Amelio (U.S. Patent 4,659,195) in view of Ueda (U.S. Patent 4,617,914) further in view of Forester et al (U.S. Patent 4,905,667) or Patel (U.S. Patent 4,577,621).

D'Amelio et al. is fundamentally different from the presently claimed invention. D'Amelio et al. requires four (4) operating cables (pull-wires) 64 to manipulate the flexible end member 60 of a borescope 34 for inspecting a jet engine. The reason for four cables is stated in the following passage from D'Amelio et al.:

> "With the cables 64 placed at spaced circumferential locations around the inner surface 66, the distal collar 58 can be moved in as many directions as there are cables. Since there are four cables at equally spaced circumferential locations in the illustrated embodiment, that construction provides movement in four different directions lying in two different intersecting planes."

If D'Amelio et al. were actually shaping and forming as required by the claims of the present application, only one of the pull-wires would be needed (as in the present application). The other three would be superfluous. Similarly, if D'Amelio et al. were shaping and forming as required by the present claims, two pull-wires would be more than sufficient. Yet D'Amelio et al. uses four. D'Amelio et al. is clearly directed to a very different device being used for a very different purpose.

As an aid to understanding the D'Amelio et al. reference, the following chart is provided which sets forth relevant passages from D'Amelio et al. and their relevance to the features of the present claims, with emphasis added:

Passage from D'Amelio et al.	**Relevance to Present Application**
"A problem arises in using presently available flexible devices for the internal inspection of complex articles of manufacture such as interior regions within jet engines. For example, certain compartments within the engine, such as the aforementioned regions within the burner cans and the turbine, are at present effectively inaccessible to viewing by an inspector. Such inaccessibility is the case even with the use of an inspection device such as an endoscope because the articulation of the inspection device requires some sort of guiding surface, such as the interior wall of the colon, to orient and support the inspection device. In contrast to the colon of the human body, a jet engine has **an interior characterized by relatively open spaces and few appropriate supporting surface readily available to guide the objective end of the inspection device**. In	This passage teaches that the D'Amelio et al. device, unlike most medical catheters, is designed to function in an environment "characterized by relatively open spaces and few appropriate supporting surface[s] readily available to guide the objective end of the inspection device." This is in contrast to the present invention. Various out-of-plane shapes interact with the walls of various human vessels. The present invention permits the formation of these shapes in situ, while the D'Amelio et al. reference teaches avoiding the walls. Note that even in the case of colonoscopy, the D'Amelio et al. reference teaches the desirability of avoiding the colon wall. See, col. 2, lines 19-22.

addition, presently known endoscope designs, even when used for their originally intended purpose, are not easily able to negotiate all colon configurations without **substantial risk of puncturing the colon wall**." Col. 2, lines 3-22.	
"Additional **problems** with the **known devices** are that the guide tube can **only articulate in two directions**, i.e. in one plane, which makes it very awkward and time consuming to get the distal end thereof in the **proper location** for feeding the viewing scope through the crossover tubes. This is generally done by lining up in the plane by which articulation of the distal end thereof is possible and then jumping or jogging the cable around to exactly line it up **so that the viewing scope can be located correctly**. Finally, the known scopes cannot easily accomplish inspections of the louvered section of the burner can or the first stage stationary vanes and first rotor as they **cannot be easily located in the center of the burner can** for ease of such inspection." Col.	Teaches the desirability of being in the "center of the burner can" for inspection. Shows that the patent is directed toward positioning the distal end ("get the distal end thereof in the proper location") rather than forming a particular shape, such as the claimed out-of-plane shapes.

3, lines 4-17.	
"The distal end is slidably inserted through a tubular elongated flexible guide member which has an operating head at a near end and a distal collar at a remote end capable of **deflecting in four discrete directions**. The objective assembly of the borescope is capable of deflecting in two discrete directions." Col. 3, lines 31-37.	Talks about deflecting in four discrete directions and two discrete directions. No hint that out-of-plane as defined in the claims is desirable or even possible with such a construction. D'Amelio et al. invention is thus directed to maximum flexibility in the placement of the distal end, not its shape.
"The device of the invention provides for a **four-way (two-plane) articulation** of the flexible guide tube whereas known devices provide for only a two-way (one-plane) articulation of the guide tube. As with the prior art, the present invention also provides for a two-way (one-plane) articulation of the viewing scope or borescope." Col. 3, lines 60-66	Talks about deflection in two different planes with the D'Amelio et al. device, but again totally fails to realize that one can achieve distal configurations that are out of either of those two planes.
"Since there are four cables at equally spaced circumferential locations in the illustrated embodiment, that construction provides **movement in four different directions** lying in two different intersecting planes." Col. 6,	Teaches movement in four different directions lying in two different intersecting planes, but again fails to even hint that the distal end can be disposed out of either of those two intersecting planes. D'Amelio contemplates

lines 27-31.	planar movement in either of two selected planes, but not an out-of-plane shape as defined by the claims.
"**Extension and retraction** of the telescoping support member 38, as shown in FIGS. 9A and 9B is effected by rotating knurled nuts 38A AND 38B to grasp and release the internal tubular members in the conventional fashion." Col. 6, lines 35-39	Knurled knobs 38A and 38B are taught as holding against longitudinal movement only. (Free to turn at another segment, which allows rotation.)
"However, it will be appreciated that even in the retracted position of the flexible body 42, the objective assembly 46 can still be manipulated to the dotted line positions indicated in FIG. 3A. In its **retracted position**, the objective assembly 46 may typically extend approximately 1.4 to 2.0 inches beyond the distal collar 58 and in the **extended position**, approximately 6 to 8 inches or longer beyond the distal collar 58." Col. 6, lines 57-65	Describes the longitudinally retracted and extended positions of the D'Amelio et al. device. Again, no reference to fixing the two parts of the device against rotation. The relevant portions of D'Amelio are always free to rotate—see discussion below.
"The retention spring 68 is preferably fashioned from flat stock so as to occupy minimal space when viewing the tubular member 60 from an end. The retention spring	Far from desiring fixing of the borescope of D'Amelio et al. against rotational movement, such rotational movement is desired to accomplish its purpose.

thus serves to retain the operating cables 64 and their surrounding outer tubes in their proper respective positions even though **the borescope 34 is twisted relative to the tubular member 60**. Specifically, the retention spring 68 prevents the operating cables 64 from spiraling with the borescope 34 **as the latter is spun inside the tubular member 60**. In the absence of the retention spring 68, the operating cables 64 would tend to **spin** with the borescope 34 which would not only cause interference between the borescope and the tubular member 60, but also would cause unreasonable and unnecessary wear on the parts." Col. 7, lines 13-25.	
"These differences include the capability of the guide member 36 having four-way, that is, two-plane articulation." Col. 7, lines 30-32.	"Reference to "two-plane articulation" but no clue that out-of-plane shaping is possible.
"In a typical maneuver, as illustrated in FIG. 13, while the objective assembly 46 is viewing the liner of the burner can 74 opposite the igniter port 76, the distal collar 58 is articulated	"Illustrates how the D'Amelio et al. device relies solely on optical feedback to place the device properly. Also illustrates that the location, not the shape, of the distal end is the

by means of the actuating knobs 62 and 63 to enable the objective assembly 46 to locate a crossover tube 78 between the adjacent burner cans 74. With continued manipulation by the operator of the inspection system 30, the distal collar 58 is moved closer to the crossover tube 78 as illustrated in FIG. 14 **while keeping the tube 78 in the center of view** of the objective assembly 46."	only thing of interest to D'Amelio et al.
"During this entire procedure, areas of interest within the burner cans can be inspected by articulating the objective assembly 46 and the distal collar 58, feeding the system 30 to an extreme end of a burner can, then extending the objective assembly 46. The inspection itself is performed as the system 30 is withdrawn from each burner can. To inspect an area around a crossover tube through which the objective assembly 46 and distal collar 58 are inserted is generally illustrated in FIG. 19. For this view, the objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 28-39	Again describes operation of the D'Amelio et al. device, and in particular teaches (with respect to Fig. 19) that the inner and outer elements "must articulate in the same plane." This is a clear teaching away from the present invention.

"There are numerous advantages inherent in the present invention over the known devices. In the first place, the four-way articulation of the steerable flexible guide member 36 allows a quicker, more **precise positioning** of its distal end before the objective assembly 46 is extended. This is important because of the **different positional locations** between the igniter port 76 and the crossover tubes 78 and other elements to be inspected by the device." Col. 8, lines 40-48.	D'Amelio et al. is teaching positioning of the distal end—not shaping. D'Amelio et al. is indifferent to the shape of the device. Position is all that matters in the D'Amelio et al. patent.
"This is done by placing the distal end of a flexible guide member 36 **in the center of the burner can** 74 as illustrated by dotted lines in FIG. 1. The invention, by virtue of its four-way articulation, permits the distal collar 58 to be easily **placed in the center of the burner can** and then to **spin or rotate** the objective assembly 46, which is positioned near the louvered area 80, in a 360 degree arc so as to inspect each one of the louvers. This easily performed operation contrasts with the prior art constructions which are restricted by a two-	Teaches placing the end of the outer element in the center of the burner can (again placement only). Also teaches free rotation of the inner element with respect to the outer element (not rotational fixing). Articulation of the outer member in four directions (apparently never at the same time) is used solely to facilitate the placement of the end of the device in the center of the burner can. At that point, the inner member is spun or rotated to observe all the louvers. This should be contrasted with applicant's out-of-plane feature, which would

way articulation at the end of their equivalent of the tubular member 60. Such prior art devices cannot be **positioned** very easily in the center of a burner can but must be **located in several positions** in order to inspect all of the louvers around the outside of the burner can." Col. 8, line 55 to col. 9, line 2.	not provide this functionality. A catheter with an out-of-plane distal tip could not, by rotation of the inner element with respect to the outer, result in observation of the various louvers. This difference is fundamental. D'Amelio et al. is interested in positioning—the present invention is directed to shaping.
"It is also noteworthy that the first stage of the jet engine 32 can be much more easily viewed by the invention. This is depicted in FIG. 21 which illustrates the distal collar 58 being **precisely located within the burner can** next to the fixed guide vanes 82 of the first stage of the jet engine 32. In this manner, the objective assembly 46 can be fed through the vanes in a precise manner and displaced accurately adjacent the first stage rotor 84. The rotor can then be turned by hand for complete inspection by the system 30. While the prior art can theoretically accomplish this end result, the fact is that in order to inspect the rotor 84 and the fixed guide vanes 82, the objective assembly 46 must repositioned several times	Teaches positioning in the center of the burner can for yet another inspection operation.

because of the awkwardness in positioning it in the first place. This awkwardness results from the limited two way articulation system previously employed. Thus, the known inspection systems must work around the area to be inspected with several positions for the end of the guide tube. In contrast, the invention merely requires that the distal collar 58 be set **near the center of the burner can** so that when the objective assembly 46 of the borescope 34 is fully extended, it will be in the precise position to get into the rotor area." Col. 9, lines 3-26.	
"Also, it should be noted that when the control head 44 is moved relative to the operating head 56 and **spun or rotated** in a concentric manner with the tubular member 60, the proximal end thereof is relatively linear and rigid. Another element of the construction of the present invention which adds considerably to the reliability of the invention is the provision of the retention spring 68 which eliminates potential problems of the operating	Again teaches free rotation of the inner element with respect to the outer element—not rotational fixing.

cables 64 twisting with the flexible body 42 as the latter is **spun or rotated** inside the tubular member 60." Col. 9, lines 46-57.	

Preliminarily, it should be noted that there is nothing in D'Amelio et al. which would motivate one of ordinary skill in the art to make any modifications to the D'Amelio et al. apparatus whatsoever. The apparatus appears to adequately solve the problems at hand, and there are no hints of any deficiencies in D'Amelio et al. Moreover, the Examiner has not pointed to anything in other prior art which would suggest making any modifications to D'Amelio et al.

The Examiner does cite the US patent classification system and Ueda for braking systems to maintain articulated curves. Although that may be true in the abstract, it is hardly true in the context of the present rejection which includes D'Amelio et al. (Of course, as pointed out above, the Examiner misreads D'Amelio et al. to include preventing rotation.) D'Amelio et al., when correctly read, teaches free rotation because that is how it works—a can is entered and the device is spun through 360 degrees to inspect the can. Adding a device to fix D'Amelio et al. against rotation is like adding a device to a paving machine to put potholes in a road—no one trying to achieve the desired result would do it. The Examiner's use of the US classification system could be appropriate in some other rejection, but not in a rejection that includes D'Amelio et al.

Turning to the D'Amelio et al. disclosure itself, in addition to Figs. 13-16 and 19, Fig. 3 is set out for convenience below. Fig. 3 gives an overview of the two major components of the D'Amelio et al. device.

FIG. 2.

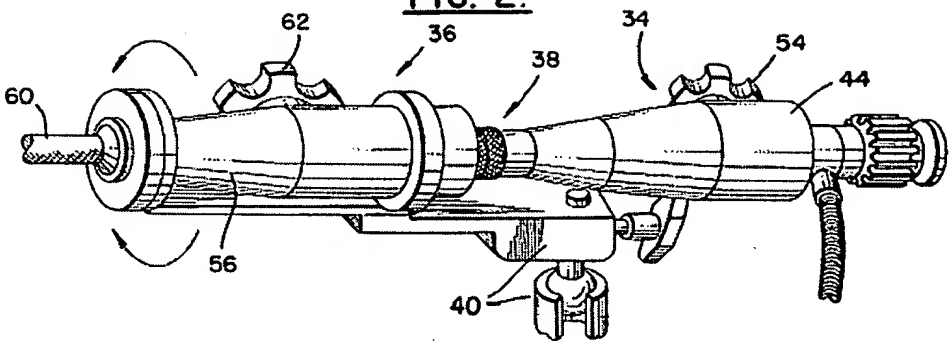
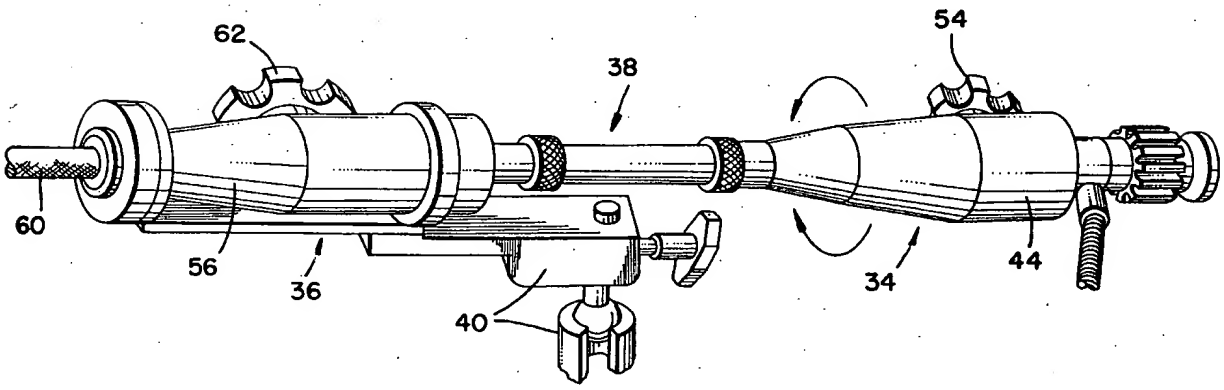


FIG. 3.



As can be seen from Figs. 2 and 3, the D'Amelio et al. device includes an inner portion (borescope 34) which is designed to be rotatable (as indicated by the arrows) with respect to an outer guide member 36. Figs. 13-16 and 19, on the other hand, illustrate various ways in which the D'Amelio et al. device is used.

FIG. 13.

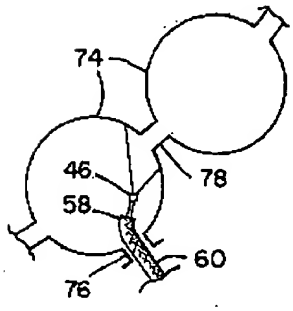


FIG. 14.

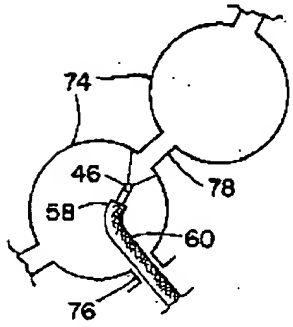


FIG. 15.

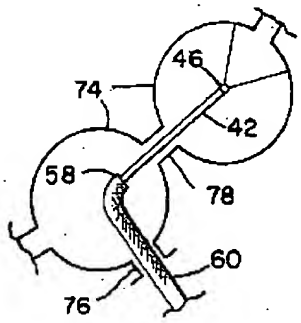


FIG. 16.

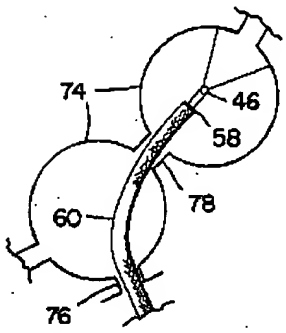
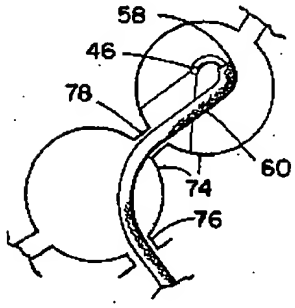


FIG. 19.



Note that claimed inventions are very different from D'Amelio et al. D'Amelio et al. is indifferent to the shapes formed by the apparatus since the D'Amelio device has direct information as to the direction in which the device is pointing. (The entire purpose of D'Amelio et al. is to point an optical inspection apparatus toward the area of interest.)

Note as well that D'Amelio et al. expressly teaches against forming out-of-plane shapes. In connection with Fig. 19, D'Amelio et al. expressly teaches that "objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 37-39. ("Guide member 36" referred to in this passage includes "tubular elongated flexible member 60" shown in Fig. 19—see col. 6, lines 5-8.) D'Amelio et al., therefore, teach directly away from the invention claimed in claim 19. D'Amelio et al. not only teaches it—it demands it, stating that the inner assembly "must" articulate in the same plane as the outer assembly. For all these reasons, the rejection over D'Amelio et al. is baseless.

Claim 19 is an independent claim that requires a catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane, and an inner medical element in the catheter tube. The claim further specifies forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. As discussed above, these references do not show—and in fact teach away from—the method in which the distal end of the combination catheter is disposed "substantially out of the first plane." Claim 19 is, therefore, allowable.

Claims 20-22, 24 and 26 all relate back to claim 19 and are allowable for the same reasons as that claim. Claim 24, in addition, requires proximally fixing the distal end of the combination catheter substantially out of the first plane. Since these references teach away from forming such an out-of-plane shape, they also teach away from fixing the combination catheter in that shape. Claim 26 also provides for proximally fixing the

inner medical element against translation and rotation with respect to the catheter tube. As discussed above, D'Amelio et al. fixes against translation but not rotation. In fact fixation against rotation is undesirable in D'Amelio et al. because of how the device is used. Any combination of references with D'Amelio et al., therefore, cannot include the required proximal fixing against rotation of claim 26. Claims 24 and 26 are allowable for these reasons as well.

Claim 28 is another independent claim. It includes the out-of-plane feature discussed above in connection with claim 19, and the proximal fixing against rotation (and translation) feature discussed above in connection with claim 26. It is allowable over these references, therefore, for the same reasons as both those claims.

Claim 29 is an independent claim that requires not only the forming of a first out-of-plane configuration, but also a second. It also requires proximal fixation against rotation (and translation) during those times when the distal end portion of the combination catheter is in the first out-of-plane configuration, and during those times when it is in the second out-of-plane configuration. These references do not teach a single out-of-plane configuration, much less two. Nor does this combination teach the requisite proximal fixing against rotation. Claim 29 is allowable for all these reasons.

Claim 32 depends form claim 19 and is allowable for the same reasons as that claim.

REJECTIONS UNDER 35 U.S.C. § 112

Whether claims 22 and 29 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner has rejected claims 22 and 29 under Sec. 112 for an alleged failure of the specification to describe the invention in such a way as to reasonably convey to one skilled in the relevant art that the inventor had, at the time the application was filed, possession of the claimed invention.

The present application has the same disclosure as that found in the parent application that is now U.S. patent 6,623,449. That disclosure provides as the fourth object:

> "A fourth object is the provision of such a catheter which can mimic almost any catheter configuration, and can **thereafter be reformed in the body to other desired shapes**."

A primary goal of the present invention, therefore, is clearly stated to be the reformation of the catheter from one "desired shape" to another "desired shape".

The specification goes on to provide that whole families of these "desired shapes" can be out of plane, as shown in the following passage:

> "Again, a whole family of these "out of plane" curves can be achieved as desired by the user by curving the sheath more or less and exposing more or less of the inner catheter or element. See FIG. 15B."

As anyone could plainly understand, the whole purpose of a "desired shape" in a catheter is to use that "desired shape" in a medical procedure—otherwise there is no good reason for forming the desired shape.

Similarly, one of the goals of the present invention is to easily and simply reshape a catheter to sequentially catheterize multiple cerebral and visceral branch arteries, as revealed in the following passage of the disclosure (again referring to the '449 patent disclosure for ease of reference):

> "Selective catheterization of cerebral and visceral branch arteries is often difficult and at times impossible in some patients--particularly older patients with very tortuous and ectatic vasculature. Successful catheterization sometimes requires multiple catheter exchanges for various shaped catheters. It is not uncommon to easily catheterize three of four vessels for a four vessel head study, only to find that the fourth vessel (generally the left or right carotid) requires an entirely different catheter shape and tip orientation. **It would be desirable if one could easily and simply reshape the catheter and reorient the tip to direct it into the vessel orifice, instead of depending on several complex catheters that require reformation, fancy torque and advancing maneuvers, body english and, above all, luck.**" (col. 1, lines 29-42).

The § 112 rejection should be reversed.

CONCLUSION

In summary, the claims on appeal are directed to methods of manipulating a combination catheter to achieve out-of-plane shapes that are not merely transitory, but rather deliberately formed and maintained so that the inner element or the combination catheter itself can be used for a medical purpose. This feature is absolutely fundamental, and is found only in the present disclosure. That the prior art lacks this feature is shown,

in part, by the multiple alternative obviousness rejections, using an even larger number of references.

Six rejections using ten references speaks eloquently to the fact that the Examiner has not, and cannot, find the presently claimed inventions in the prior art. This feature, absent from the art, provides shapes for specific purposes, such as anchorage or wedging of the catheter in a desired location, which heretofore have required specially designed preformed catheter shapes to achieve.

The prior art is very different. Sylvanowicz points to the left or right coronary arteries and extends an inner catheter toward the ostia using respective planar shapes with one functionally straight element and one curved element (Syl., col. 7, ll. 46-52). The inner catheter and outer tube in Sylvanowicz are co-linear at the point where the inner catheter exits the outer tube. Both are specified as pointing to the right coronary ostium. If the distal portion of the inner catheter points toward the right coronary ostium, and the straight distal segment 62 points toward the rights coronary ostium, then those two elements **must be in the same plane**. The Examiner's position to the contrary is not well-taken. Petruzzi points to the ampulla of Vater and a catheter is extended from the distal tip in the plane of sight out the device into the common bile duct, using one functionally straight element and one curved element (Pet., col. 1, ll. 59-62). The catheter in Cho is pointed in a right-hand lateral or left-hand lateral direction in a single plane of a body cavity with one straight and one curved element (Cho, col. 4, ll. 60-68, col. 5, ll. 1-9). D'Amelio points backward to inspect (in Fig. 19), with two curved elements that are specifically required to be in plane. In D'Amelio, either element could have more or less curvature than is shown in Fig. 19—the exact shape of the combination

being unknown and unknowable in D'Amelio, since the only feature of importance in that reference is whether the desired area of inspection is in view. This is very different from the present invention where the goal is the out-of-plane shape, not the direction of pointing. (D'Am., col. 8, ll. 34-39). Moreover, the endoscopic art (including Petruzzi, Cho and D'Amelio) provide stable, **stationary** platforms from which an inner element is **moved** to a desired location. The present invention, on the other hand, is directed to inner elements that are **fixed** and maintained in an out-of-plane shape with respect to the outer element. Note that if the inner curved element in the present invention were moved with respect to the outer tube after the shape was formed, it would no longer be "fixed" in the out-of-plane shape. It would have moved to a different, out-of-plane shape with respect to the outer tube. **The present invention and the endoscopy art are simply two different things entirely.**

Shaping, particularly to fix a desired out-of-plane shape into the combination catheter for use in a medical procedure, is the clear distinction of the present invention over the prior art. The present invention is not directed to pointing, aiming, guiding, or steering. The prior art is, but the present invention is not. This distinction, and the invention itself, are fully and clearly articulated in the following passages from the present specification:

> "As will become apparent in view of the following disclosure, manipulation of catheter 31 results in mimicking virtually any simple or complex curved configuration of selective arterial catheter shape imaginable while the catheter is disposed in the patient." Page 8, lines 18-20.

"Tip reorientation, the goal of most prior devices which have addressed the problem, is only half of what is needed to make a truly workable universal catheter. Numerous catheter configurations have been conceived not only to reorient the tip properly for selection of branch vessels, but also to provide anchorage of the catheter against the aortic wall." Page 1, lines 24-27

"These complex configurations, therefore, evolved not only to orient the tip properly, but also to wedge the catheter securely in the branch vessel. Other devices which simply modify the distal catheter curve may aid in tip orientation for vessel selection, but fail to provide the anchorage which is necessary to prevent catheter dislodgement." Page 2, lines 6-9.

The presently claimed invention constitutes a new, nonobvious and useful method—a true invention which is both elegantly simple and simply elegant. This invention is not shown or suggested in the prior art. Any one of the following features of the present claims would be sufficient to distinguish the art:

- two curved distal end portions interacting and
- fixed together
- to form an out-of-plane shape
- which out-of-plane shape is used in a medical procedure.

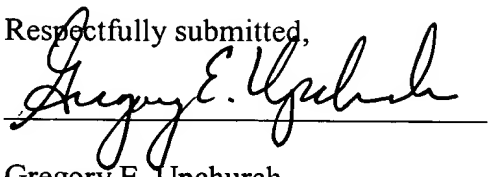
Many of the claims include several of them. The claims are allowable over this art.

Given the Office's renewed **emphasis on the independent inventor and increased quality in examination**, all of these rejections should be overturned.

Reversal of the Examiner, therefore, is solicited.

The Office is hereby authorized to charge deposit account #08-3460 for any additional fees required.

Respectfully submitted,



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IX. CLAIMS APPENDIX

The text of the claims involved in the appeal is as follows:

19. The method of using a combination catheter having a catheter tube and an inner medical element, said combination catheter having a proximal end and a distal end, the method comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end;

forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.

20. The method of using a combination catheter as set forth in claim 19 further including the step of positioning the combination catheter in a desired position, and using the combination catheter in a medical procedure while the distal end of the combination catheter is disposed substantially out of the first plane.

21. The method of using a combination catheter as set forth in claim 20 further including the step of reforming the distal end of the combination catheter into a substantially different shape.

22. The method of using a combination catheter as set forth in claim 21 further including the step of using the combination catheter in a medical procedure while the distal end of the combination catheter is in the reformed shape.

24. The method as set forth in claim 19 further including proximally fixing the distal end of the combination catheter substantially out of the first plane.

26. The method as set forth in claim 19 further including proximally fixing the inner medical element against translation and rotation with respect to the catheter tube.

28. The method of using a combination catheter having a catheter tube and an inner medical element, said combination catheter having a proximal end and a distal end, the method comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end;

forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element; and

proximally fixing the inner medical element against translation and rotation with respect to the catheter tube.

29. The method of using a combination catheter having a catheter tube and an inner medical element, said combination catheter having a proximal end and a distal end, the method comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end;

forming the combination catheter into a first shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element;

proximally fixing the inner medical element against translation and rotation with respect to the catheter tube while the distal end of the combination catheter is disposed substantially out of the first plane;

forming the combination catheter into a second shape, different from the first shape, in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element;

proximally fixing the inner medical element against translation and rotation with respect to the catheter tube while the distal end of the combination catheter is disposed in the second shape.

32. The method as set forth in claim 19 wherein the forming step includes rotating the inner medical element with respect to the catheter tube.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.